510(k) Summary

DEC 07 2012

Submitter:	Zimmer Spine 5301 Riata Park Court, Bldg F Austin, TX 78727
Author:	Jennifer Tribbett Senior Regulatory Affairs Specialist
Contact Person:	Jennifer Tribbett Senior Regulatory Affairs Specialist Telephone: (512) 533-1061 Fax: (512) 219-5463
Date:	September 5, 2012
Trade Name:	V2F™ Anterior Fixation System
Common Name:	Spinal Fixation System
Classification Name and Reference:	Orthosis, Spinal Intervertebral Fixation 21 CFR § 888.3060, KWQ, Class II
Predicate(s):	•InCompass Spinal Fixation System (K021564) •Synthes Thoracolumbar Spine Locking Plate (TSLP) System (K020244)

Device Description:

The V2F™ Anterior Fixation System is a temporary supplemental fixation device consisting of: thoracolumbar plates, cap screws, bone screws and instrumentation necessary for implantation of the system.

The V2F™ Anterior Fixation System is used as an implant for the correction and stabilization of the spine. This system provides temporary stabilization and augments the development of a solid spinal fusion. Additionally, this system provides the surgeon with the ability to supplement an interbody device with anterior plate fixation. The plates are low profile and anatomically designed to provide optimal fit from either anterior or anterior-lateral approach. All implant components are manufactured from titanium alloy as specified in ASTM F136.

Indications for Use:

The V2F™ Anterior Fixation System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis or a failed previous spine surgery.

Performance Data:

ASTM F1717 static compression bending, static torsion and dynamic compression bending were performed to establish substantial equivalence. The test results demonstrate that the V2F™ Anterior Fixation System functioned as intended and performed in a manner substantially equivalent to that of the predicate(s).

Basis of Substantial Equivalence:

The V2F™ Anterior Fixation System is similar to the predicate devices with respect to technical characteristics, design, materials, performance and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: December 7, 2012

Zimmer Spine
% Mr. Ron Yarbrough
Director of Regulatory Affairs
5301 Riata Park Court, Building F
Austin, Texas 78727

Re: K122733
Trade/Device Name: V2F™ Anterior Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 18, 2012
Received: October 24, 2012

Dear Mr. Yarbrough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopaedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: V2F™ Anterior Fixation System

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Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Caroline Rhim -S

(Division Sign-Off)
Division of Orthopedic Devices
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